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AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

BETTY DAVIS-BARBOSA, et al.,

Plaintiffs,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.),
and MONSANTO COMPANY,

Defendants.

) MDL Docket No. 1699
)
) CASE NO. 3:07-cv-6329-CRB
)
) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**
)
) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (formerly known as "Monsanto Company"¹)
3 ("Pharmacia"), and G.D. Searle LLC ("Searle"), (collectively "Defendants") and file their
4 Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as
5 follows:

6 **I.**

7 **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used
9 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted
10 generally. Defendants may seek leave to amend this Answer when discovery reveals the
11 specific time periods in which Plaintiffs were prescribed and used Celebrex®.

12 **II.**

13 **ANSWER**

14 **Response to Allegations Regarding Parties**

15 1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but
16 deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain
17 periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United
18 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
19 accordance with their approval by the FDA. Defendants admit that, during certain periods of
20 time, Celebrex® were manufactured and packaged for Searle, which developed, tested,
21 marketed, co-promoted, and distributed Celebrex® in the United States to be prescribed by
22 healthcare providers who are by law authorized to prescribe drugs in accordance with their
23 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used
24

25 ¹ Plaintiffs' Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity
26 known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31,
27 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company,
28 Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag
Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the
agricultural business and does not and has not ever designed, produced, manufactured, sold, resold, or distributed
Celebrex®. Given that Plaintiffs allege in their Complaint that Monsanto Company was involved in distributing
Celebrex®, see PLAINTIFFS' COMPLAINT at ¶ 10, Defendants assume Plaintiffs mean to refer to 1933 Monsanto.
As a result, Pharmacia will respond to the allegations directed at Monsanto Company.

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1 in accordance with its FDA-approved prescribing information. Defendants state that the
2 potential effects of Celebrex® were and are adequately described in its FDA-approved
3 prescribing information, which was at all times adequate and comported with applicable
4 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused
5 Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the
6 Complaint.

7 2. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
9 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
10 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
11 damages, and deny the remaining allegations in this paragraph of the Complaint.

12 3. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
14 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
15 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
16 damages, and deny the remaining allegations in this paragraph of the Complaint.

17 4. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
19 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
20 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
21 damages, and deny the remaining allegations in this paragraph of the Complaint.

22 5. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
24 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
25 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
26 damages, and deny the remaining allegations in this paragraph of the Complaint.

27 6. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,

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1 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
2 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
3 damages, and deny the remaining allegations in this paragraph of the Complaint.

4 7. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,
6 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.
7 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
8 damages, and deny the remaining allegations in this paragraph of the Complaint.

9 8. Defendants admit that Pfizer is a Delaware corporation with its principal place of
10 business in New York. Defendants admit that, as the result of a merger in April 2003,
11 Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph
12 of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants
13 are without knowledge or information sufficient to form a belief as to the truth of such
14 allegations, and, therefore, deny the same. Defendants admit that, during certain periods of
15 time, Pfizer marketed and co-promoted Celebrex® in the United States, including California, to
16 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
17 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
18 paragraph of the Complaint.

19 9. Defendants admit that Searle is a Delaware limited liability company with its principal
20 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,
21 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
22 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
23 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
24 Celebrex® in the United States to be prescribed by healthcare providers who are by law
25 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
26 the remaining allegations in this paragraph of the Complaint.

27 10. Defendants admit that in 1933 an entity known as Monsanto Company ("1933
28 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of

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1 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name
2 to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company,
3 was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company
4 changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged
5 in the agricultural business and does not and has not ever manufactured, marketed, sold, or
6 distributed Celebrex®. The 2000 Monsanto is not and has never been the parent of either
7 Searle or Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed,
8 sold, or distributed Celebrex®, Defendants therefore state that the 2000 Monsanto is not a
9 proper party in this matter. Defendants deny the remaining allegations in this paragraph of the
10 Complaint. Defendants state that the response to this paragraph of the Complaint regarding
11 Monsanto is incorporated by reference into Defendants' responses to each and every paragraph
12 of the Complaint referring to Monsanto and/or Defendants.

13 11. Defendants admit that Pharmacia is a Delaware corporation with its principal place of
14 business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as
15 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
16 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted
17 Celebrex® in the United States, including California, to be prescribed by healthcare providers
18 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.
19 Defendants deny the remaining allegations in this paragraph of the Complaint.

20 **Response to Allegations Regarding Jurisdiction and Venue**

21 12. Defendants are without knowledge or information to form a belief as to the truth of the
22 allegations in this paragraph of the Complaint regarding the amount in controversy, and,
23 therefore, deny that the same. However, Defendants admit that Plaintiffs claim that the amount
24 in controversy exceeds \$75,000, exclusive of interests and costs.

25 13. Defendants are without knowledge or information to form a belief as to the truth of the
26 allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and the amount
27 in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim
28 that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of

1 interests and costs.

2 14. Defendants are without knowledge or information to form a belief as to the allegations
3 in this paragraph of the Complaint regarding the judicial district in which the asserted claims
4 allegedly arose and, therefore, deny the same. Defendants state that Celebrex® was and is safe
5 and effective when used in accordance with its FDA-approved prescribing information.
6 Defendants deny committing a tort in the States of California, Minnesota, Florida, Washington,
7 Wisconsin, and Michigan, and deny the remaining allegations in this paragraph of the
8 Complaint.

9 15. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
10 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
11 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
12 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
13 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
14 Celebrex® in the United States to be prescribed by healthcare providers who are by law
15 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
16 that Pfizer, Pharmacia, and Searle are registered to and do business in the State of and
17 California. Defendants state that the allegations in this paragraph of the Complaint regarding
18 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
19 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
20 the same. Defendants deny committing a tort in the States of California, Minnesota, Florida,
21 Washington, Wisconsin, and Michigan, and deny the remaining allegations in this paragraph of
22 the Complaint.

23 **Response to Allegations Regarding Interdistrict Assignment**

24 16. Defendants state that this paragraph of the Complaint contains legal contentions to
25 which no response is required. To the extent that a response is deemed required, Defendants
26 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
27 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
28 Panel on Multidistrict Litigation on September 6, 2005.

Response to Factual Allegations

17. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

18. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

19. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

20. Defendants state that the allegations in this paragraph of the Complaint regarding aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as being non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendants deny the remaining allegations in this paragraph of the Complaint.

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21. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

22. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

19. Answering the second Paragraph 19 of the Complaint, Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

20. Answering the second Paragraph 20 of the Complaint, Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

21. Answering the second Paragraph 21 of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding “other pharmaceutical companies” are not directed towards Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at

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1 therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1)
2 isoenzyme.” Plaintiffs fail to provide the proper context for the remaining allegations in this
3 paragraph and Defendants therefore lack sufficient information or knowledge to form a belief
4 as to the truth of the allegations and, therefore, deny the remaining allegations in this paragraph
5 of the Complaint.

6 22. Answering the second Paragraph 22 of the Complaint, Defendants state that the
7 allegations in this paragraph of the Complaint regarding “predecessors in interest” are vague
8 and ambiguous. Defendants are without knowledge or information sufficient to form a belief as
9 to the truth of such allegations, and, therefore, deny the same. Defendants state that, as stated in
10 the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed
11 to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2
12 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the
13 cyclooxygenase-1 (COX-1) isoenzyme.” Defendants state that Celebrex® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
18 remaining allegations in this paragraph of the Complaint.

19 23. Defendants admit that Searle submitted a New Drug Application (“NDA”) for
20 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted
21 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of
22 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.
23 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to
24 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis
25 (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny
26 the remaining allegations in this paragraph of the Complaint.

27 24. Defendants admit that Celebrex® was launched in February 1999. Defendants admit
28 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted

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1 Celebrex® in the United States to be prescribed by healthcare providers who are by law
2 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
3 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
4 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
5 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
6 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe
7 and effective when used in accordance with its FDA-approved prescribing information.
8 Defendants state that the potential effects of Celebrex® were and are adequately described in its
9 FDA-approved prescribing information, which was at all times adequate and comported with
10 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
11 remaining allegations in this paragraph of the Complaint.

12 25. Defendants state that the referenced article speaks for itself and respectfully refer the
13 Court to the article for its actual language and text. Any attempt to characterize the article is
14 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
16 this paragraph of the Complaint.

17 26. Defendants state that the referenced article speaks for itself and respectfully refer the
18 Court to the article for its actual language and text. Any attempt to characterize the article is
19 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
21 this paragraph of the Complaint.

22 27. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny the allegations in this paragraph of the Complaint.

27 28. Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
4 the Complaint.

5 29. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA
6 on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to
7 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,
8 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself
9 and respectfully refer the Court to the study for its actual language and text. Any attempt to
10 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of
11 the Complaint.

12 30. Defendants state that the referenced Medical Officer Review speaks for itself and
13 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
14 attempt to characterize the Medical Officer Review is denied. Defendants state that the
15 referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court
16 to the Alert for Healthcare Professionals for its actual language and text. Any attempt to
17 characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining
18 allegations in this paragraph of the Complaint.

19 31. Defendants state that the referenced study speaks for itself and respectfully refer the
20 Court to the study for its actual language and text. Any attempt to characterize the study is
21 denied. Defendants state that the referenced article speaks for itself and respectfully refer the
22 Court to the article for its actual language and text. Any attempt to characterize the article is
23 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
24 paragraph of the Complaint.

25 32. Defendants state that the referenced Medical Officer Review speaks for itself and
26 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
27 attempt to characterize the Medical Officer Review is denied. Defendants state that the
28 referenced article speaks for itself and respectfully refer the Court to the article for its actual

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1 language and text. Any attempt to characterize the article is denied. Defendants deny the
2 remaining allegations in this paragraph of the Complaint.

3 33. Defendants state that the referenced article speaks for itself and respectfully refer the
4 Court to the article for its actual language and text. Any attempt to characterize the article is
5 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
6 paragraph of the Complaint.

7 34. Defendants state that the referenced articles speak for themselves and respectfully refer
8 the Court to the articles for their actual language and text. Any attempt to characterize the
9 articles is denied. Defendants state that the referenced study speaks for itself and respectfully
10 refer the Court to the study for its actual language and text. Any attempt to characterize the
11 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

12 35. Defendants state that the referenced Medical Officer Review speaks for itself and
13 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
14 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
15 allegations in this paragraph of the Complaint.

16 36. Plaintiffs fail to provide the proper context for the allegations concerning “Public
17 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
18 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
19 Defendants deny the remaining allegations in this paragraph of the Complaint.

20 37. Defendants state that the referenced study speaks for itself and respectfully refer the
21 Court to the study for its actual language and text. Any attempt to characterize the study is
22 denied. Plaintiffs fail to provide the proper context for the allegations concerning “Public
23 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
24 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
25 Defendants deny the remaining allegations in this paragraph of the Complaint.

26 38. Defendants admit that there was a clinical trial called APC. Defendants state that the
27 referenced article speaks for itself and respectfully refer the Court to the article for its actual
28 language and text. Any attempt to characterize the article is denied. Defendants deny the

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1 remaining allegations in this paragraph of the Complaint.

2 39. Defendants admit that there was a clinical trial called APC. Defendants state that the
3 referenced article speaks for itself and respectfully refer the Court to the article for its actual
4 language and text. Any attempt to characterize the article is denied. Defendants deny the
5 remaining allegations in this paragraph of the Complaint.

6 40. Defendants state that the referenced Medical Officer Review speaks for itself and
7 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
8 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
9 allegations in this paragraph of the Complaint.

10 41. Defendants state that the referenced FDA Class Review speaks for itself and
11 respectfully refer the Court to the CLASS Review for its actual language and text. Any attempt
12 to characterize the CLASS Review is denied. Defendants deny the remaining allegations in this
13 paragraph of the Complaint.

14 42. Defendants admit that there was a clinical trial called PreSAP. Plaintiffs fail to provide
15 the proper context for the allegations concerning “other Celebrex trials” contained in this
16 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
17 form a belief as to the truth of such allegations and, therefore, deny the same. As for the
18 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state
19 that the referenced study speaks for itself and respectfully refer the Court to the study for its
20 actual language and text. Any attempt to characterize the study is denied. Defendants deny the
21 remaining allegations in this paragraph of the Complaint.

22 43. Defendants state that the referenced article speaks for itself and respectfully refer the
23 Court to the article for its actual language and text. Any attempt to characterize the article is
24 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 44. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the
26 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
27 therefore lack sufficient information or knowledge to form a belief as to the truth of such
28 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for

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1 themselves and respectfully refer the Court to the studies for their actual language and text.
2 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in
3 this paragraph of the Complaint.

4 45. Defendants state that the referenced Medical Officer Review speaks for itself and
5 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
6 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
7 allegations in this paragraph of the Complaint.

8 46. Defendants state that allegations in this paragraph of the Complaint regarding Vioxx®
9 in this paragraph of the Complaint are not directed toward Defendants, and therefore no
10 response is required. To the extent that a response is deemed required, Plaintiffs fail to provide
11 the proper context for the allegations in this paragraph of the Complaint regarding Vioxx® in
12 this paragraph of the Complaint. Defendants therefore lack sufficient information or
13 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
14 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
15 the study for its actual language and text. Any attempt to characterize the study is denied.
16 Defendants deny the remaining allegations in this paragraph of the Complaint.

17 47. Defendants state that allegations in this paragraph of the Complaint regarding Merck
18 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and
19 therefore no response is required. To the extent that a response is deemed required, Plaintiffs
20 fail to provide the proper context for the allegations in this paragraph of the Complaint
21 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack
22 sufficient information or knowledge to form a belief as to the truth of such allegations and,
23 therefore, deny the same. Defendants state that the referenced study speaks for itself and
24 respectfully refer the Court to the study for its actual language and text. Any attempt to
25 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of
26 the Complaint.

27 48. Defendants state that allegations in this paragraph of the Complaint regarding Merck
28 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and

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1 therefore no response is required. To the extent that a response is deemed required, Plaintiffs
2 fail to provide the proper context for the allegations in this paragraph of the Complaint
3 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack
4 sufficient information or knowledge to form a belief as to the truth of such allegations and,
5 therefore, deny the same. Defendants state that the referenced study speaks for itself and
6 respectfully refer the Court to the study for its actual language and text. Any attempt to
7 characterize the study is denied. Defendants state that the referenced article speaks for itself
8 and respectfully refer the Court to the article for its actual language and text. Any attempt to
9 characterize the article is denied. Defendants deny the remaining allegations in this paragraph
10 of the Complaint.

11 49. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants deny the allegations in this
13 paragraph of the Complaint.

14 50. Defendants state that the referenced article speaks for itself and respectfully refer the
15 Court to the article for its actual language and text. Any attempt to characterize the article is
16 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

17 51. Defendants state that allegations in this paragraph of the Complaint are not directed
18 toward Defendants, and therefore no response is required. To the extent that a response is
19 deemed required, Defendants state that the referenced article speaks for itself and respectfully
20 refer the Court to the article for its actual language and text. Any attempt to characterize the
21 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 52. Defendants deny the allegations in this paragraph of the Complaint.

23 53. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
28 remaining allegations contained in this paragraph of the Complaint.

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1 54. Defendants deny any wrongful conduct and deny the allegations contained in this
2 paragraph of the Complaint.

3 55. Defendants deny any wrongful conduct and deny the allegations contained in this
4 paragraph of the Complaint.

5 56. Defendants state that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct and deny the remaining allegations contained in this
10 paragraph of the Complaint.

11 57. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
13 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
18 Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of
19 the Complaint.

20 58. Defendants admit that the FDA Division of Drug Marketing, Advertising, and
21 Communications (“DDMAC”) sent a letter to Pfizer dated January 10, 2005. Defendants state
22 that the referenced letter speaks for itself and respectfully refer the Court to the letter for its
23 actual language and text. Any attempt to characterize the letter is denied. Defendants admit
24 that the DDMAC sent a letter to Searle dated October 6, 1999. Defendants state that the
25 referenced letter speaks for itself and respectfully refer the Court to the letter for its actual
26 language and text. Any attempt to characterize the letter is denied. Defendants state that the
27 transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and
28 respectfully refer the Court to the transcripts for their actual language and text. Any attempt to

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1 characterize the transcripts is denied. Defendants state that the referenced study speaks for
2 itself and respectfully refer the Court to the article for its actual language and text. Any attempt
3 to characterize the article is denied. Defendants deny the remaining allegations in this
4 paragraph of the Complaint.

5 59. Defendants state that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
10 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
11 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
12 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
13 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
14 United States to be prescribed by healthcare providers who are by law authorized to prescribe
15 drugs in accordance with their approval by the FDA. Defendants deny the remaining
16 allegations in this paragraph of the Complaint.

17 60. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
22 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
23 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
24 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
25 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
26 United States to be prescribed by healthcare providers who are by law authorized to prescribe
27 drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a
28 prescription medication which is approved by the FDA for the following indications: (1) for

1 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of
2 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the
3 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps
4 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic
5 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for
6 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age
7 and older. Defendants deny any wrongful conduct and deny the remaining allegations in this
8 paragraph of the Complaint.

9 61. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,
12 which at all times was adequate and comported with applicable standards of care and law.
13 Defendants state that Plaintiffs' allegations in this paragraph of the Complaint regarding
14 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or
15 information to form a belief as to the truth of such allegations, and, therefore, deny the same.
16 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
17 allegations in this paragraph of the Complaint.

18 62. Defendants state that Celebrex® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
23 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
24 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
25 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
26 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
27 United States to be prescribed by healthcare providers who are by law authorized to prescribe
28 drugs in accordance with their approval by the FDA. Defendants deny the remaining

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1 allegations in this paragraph of the Complaint.

2 63. Defendants state that Celebrex® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,
5 which at all times was adequate and comported with applicable standards of care and law.
6 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
7 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
8 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
9 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
10 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
11 United States to be prescribed by healthcare providers who are by law authorized to prescribe
12 drugs in accordance with their approval by the FDA. Defendants deny the remaining
13 allegations in this paragraph of the Complaint.

14 64. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
19 the Complaint.

20 65. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
25 the Complaint.

26 66. Defendants deny the allegations in this paragraph of the Complaint.

27 67. Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
4 the Complaint.

5 68. Defendants state that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
10 the Complaint.

11 69. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
13 Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
14 Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations in this
15 paragraph of the Complaint.

16 70. Defendants state that Celebrex® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
21 remaining allegations in this paragraph of the Complaint.

22 71. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® are and were adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 72. Defendants state that Celebrex® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Celebrex® are and were adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
5 the study for its actual language and text. Any attempt to characterize the study is denied.
6 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
7 the Complaint.

8 73. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
10 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
11 effective when used in accordance with its FDA-approved prescribing information. Defendants
12 state that the potential effects of Celebrex® are and were adequately described in its FDA-
13 approved prescribing information, which was at all times adequate and comported with
14 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
15 remaining allegations in this paragraph of the Complaint.

16 **Response to First Cause of Action: Negligence**

17 74. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
18 Complaint as if fully set forth herein.

19 75. Defendants state that this paragraph of the Complaint contains legal contentions to
20 which no response is required. To the extent that a response is deemed required, Defendants
21 admit that they had duties as are imposed by law but deny having breached such duties.
22 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
23 FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 76. Defendants state that this paragraph of the Complaint contains legal contentions to

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1 which no response is required. To the extent that a response is deemed required, Defendants
2 admit that they had duties as are imposed by law but deny having breached such duties.
3 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
4 FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
8 the Complaint.

9 77. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
11 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
16 remaining allegations in this paragraph of the Complaint, including all subparts.

17 78. Plaintiffs' Complaint omits Paragraph 78.

18 79. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
20 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
21 effective when used in accordance with its FDA-approved prescribing information. Defendants
22 state that the potential effects of Celebrex® were and are adequately described in its FDA-
23 approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
25 remaining allegations in this paragraph of the Complaint.

26 80. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 81. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
6 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
7 effective when used in accordance with its FDA-approved prescribing information. Defendants
8 state that the potential effects of Celebrex® were and are adequately described in its FDA-
9 approved prescribing information, which was at all times adequate and comported with
10 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
11 Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations in this
12 paragraph of the Complaint.

13 82. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
15 Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
16 Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations in this
17 paragraph of the Complaint.

18 83. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
19 damages, and deny the remaining allegations in this paragraph of the Complaint.

20 84. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
21 damages, and deny the remaining allegations in this paragraph of the Complaint.

22 **Response to Second Cause of Action: Strict Liability**

23 85. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
24 Complaint as if fully set forth herein.

25 86. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
27 Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of
28 time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be

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1 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
2 with their approval by the FDA. Defendants admit that, during certain periods of time,
3 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
4 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
5 providers who are by law authorized to prescribe drugs in accordance with their approval by the
6 FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
7 consumers without substantial change from the time of sale. Defendants deny the remaining
8 allegations in this paragraph of the Complaint.

9 87. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny the remaining allegations in this paragraph of the Complaint.

14 88. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
19 remaining allegations in this paragraph of the Complaint.

20 89. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
25 remaining allegations in this paragraph of the Complaint, including all subparts.

26 90. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny that Celebrex® is unreasonably dangerous and deny the remaining allegations
3 in this paragraph of the Complaint.

4 91. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
6 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
7 effective when used in accordance with its FDA-approved prescribing information. Defendants
8 state that the potential effects of Celebrex® were and are adequately described in its FDA-
9 approved prescribing information, which was at all times adequate and comported with
10 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
11 Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damages, and deny the
12 remaining allegations in this paragraph of the Complaint.

13 92. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
18 remaining allegations in this paragraph of the Complaint.

19 93. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
26 Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damages, and deny the
27 remaining allegations in this paragraph of the Complaint.

28 94. Defendants state that Celebrex® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 95. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
8 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
9 effective when used in accordance with its FDA-approved prescribing information. Defendants
10 state that the potential effects of Celebrex® were and are adequately described in its FDA-
11 approved prescribing information, which was at all times adequate and comported with
12 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
13 Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations in this
14 paragraph of the Complaint.

15 96. Defendants state that Celebrex® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
20 the Complaint.

21 97. Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
23 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
24 effective when used in accordance with its FDA-approved prescribing information. Defendants
25 state that the potential effects of Celebrex® were and are adequately described in its FDA-
26 approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
28 remaining allegations in this paragraph of the Complaint.

1 98. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
2 damages, and deny the remaining allegations in this paragraph of the Complaint.

3 99. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
4 damages, and deny the remaining allegations in this paragraph of the Complaint.

5 100. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
6 damages, and deny the remaining allegations in this paragraph of the Complaint.

7 **Response to Third Cause of Action: Breach of Express Warranty**

8 101. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
9 Complaint as if fully set forth herein.

10 102. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
12 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants admit that they provided FDA-approved
17 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
18 this paragraph of the Complaint.

19 103. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants admit that they provided FDA-approved
26 prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and
27 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

28 104. Defendants admit that they provided FDA-approved prescribing information regarding

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1 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this
2 paragraph of the Complaint.

3 105. Defendants state that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
8 the Complaint.

9 106. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
14 the Complaint.

15 107. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
17 Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants admit that they provided FDA-approved prescribing information regarding
21 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 108. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
23 damages, and deny the remaining allegations in this paragraph of the Complaint.

24 109. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
25 damages, and deny the remaining allegations in this paragraph of the Complaint.

26 110. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
27 damages, and deny the remaining allegations in this paragraph of the Complaint.
28

Response to Fourth Cause of Action: Breach of Implied Warranty

111. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

112. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

113. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

114. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

115. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with

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1 applicable standards of care and law. Defendants admit that they provided FDA-approved
2 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
3 this paragraph of the Complaint.

4 116. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
6 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,
7 Celebrex® was expected to reach users and consumers without substantial change from the
8 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

9 117. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
11 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct, deny that they
16 breached any warranty, and deny the remaining allegations in this paragraph of the Complaint.

17 118. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
18 damages, and deny the remaining allegations in this paragraph of the Complaint.

19 119. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
20 damages, and deny the remaining allegations in this paragraph of the Complaint.

21 120. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
22 damages, and deny the remaining allegations in this paragraph of the Complaint.

23 **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

24 121. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
25 Complaint as if fully set forth herein.

26 122. Defendants state that this paragraph of the Complaint contains legal contentions to
27 which no response is required. To the extent that a response is deemed required, Defendants
28 admit that they had duties as are imposed by law but deny having breached such duties.

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1 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
2 FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 123. Defendants state that Celebrex® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
12 the Complaint, including all subparts.

13 124. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 125. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
21 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
26 Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this
27 paragraph of the Complaint.

28 126. Defendants state that Celebrex® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 127. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
8 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
9 effective when used in accordance with its FDA-approved prescribing information. Defendants
10 state that the potential effects of Celebrex® were and are adequately described in its FDA-
11 approved prescribing information, which was at all times adequate and comported with
12 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
13 remaining allegations in this paragraph of the Complaint.

14 128. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
16 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
17 effective when used in accordance with its FDA-approved prescribing information. Defendants
18 state that the potential effects of Celebrex® were and are adequately described in its FDA-
19 approved prescribing information, which was at all times adequate and comported with
20 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
21 remaining allegations in this paragraph of the Complaint.

22 129. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
24 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
25 effective when used in accordance with its FDA-approved prescribing information. Defendants
26 state that the potential effects of Celebrex® were and are adequately described in its FDA-
27 approved prescribing information, which was at all times adequate and comported with
28 applicable standards of care and law. Defendants deny any wrongful conduct and deny the

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1 remaining allegations in this paragraph of the Complaint.

2 130. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
4 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
5 effective when used in accordance with its FDA-approved prescribing information. Defendants
6 state that the potential effects of Celebrex® were and are adequately described in its FDA-
7 approved prescribing information, which was at all times adequate and comported with
8 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
9 remaining allegations in this paragraph of the Complaint.

10 131. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
12 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
17 remaining allegations in this paragraph of the Complaint.

18 132. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
20 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
21 effective when used in accordance with its FDA-approved prescribing information. Defendants
22 state that the potential effects of Celebrex® were and are adequately described in its FDA-
23 approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
25 remaining allegations in this paragraph of the Complaint.

26 133. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
27 damages, and deny the remaining allegations in this paragraph of the Complaint.

28 134. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or

1 damages, and deny the remaining allegations in this paragraph of the Complaint.

2 135. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
3 damages, and deny the remaining allegations in this paragraph of the Complaint.

4 **Response to Sixth Cause of Action: Unjust Enrichment**

5 136. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
6 Complaint as if fully set forth herein.

7 137. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
8 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
9 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
10 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
11 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
12 Celebrex® in the United States to be prescribed by healthcare providers who are by law
13 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
14 the remaining allegations in this paragraph of the Complaint.

15 138. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
17 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this
18 paragraph of the Complaint.

19 139. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
21 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this
22 paragraph of the Complaint.

23 140. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
25 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
26 effective when used in accordance with its FDA-approved prescribing information. Defendants
27 state that the potential effects of Celebrex® were and are adequately described in its FDA-
28 approved prescribing information, which was at all times adequate and comported with

1 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
2 remaining allegations in this paragraph of the Complaint.

3 141. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
5 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
6 effective when used in accordance with its FDA-approved prescribing information. Defendants
7 state that the potential effects of Celebrex® were and are adequately described in its FDA-
8 approved prescribing information, which was at all times adequate and comported with
9 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
10 remaining allegations in this paragraph of the Complaint.

11 142. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
12 damages, and deny the remaining allegations in this paragraph of the Complaint.

13 **Response to Prayer for Relief**

14 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
15 damages, and deny the remaining allegations in paragraph of the Complaint headed “Prayer for
16 Relief,” including all subparts.

17 **III.**

18 **GENERAL DENIAL**

19 Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs’
20 Complaint that have not been previously admitted, denied, or explained.

21 **IV.**

22 **AFFIRMATIVE DEFENSES**

23 Defendants reserve the right to rely upon any of the following or additional defenses to
24 claims asserted by Plaintiffs to the extent that such defenses are supported by information
25 developed through discovery or evidence at trial. Defendants affirmatively show that:

26 **First Defense**

27 1. The Complaint fails to state a claim upon which relief can be granted.
28

1 **Second Defense**

2 2. Celebrex® is a prescription medical product. The federal government has preempted
3 the field of law applicable to the labeling and warning of prescription medical products.
4 Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable
5 federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon
6 which relief can be granted; such claims, if allowed, would conflict with applicable federal law
7 and violate the Supremacy Clause of the United States Constitution.

8 **Third Defense**

9 3. At all relevant times, Defendants provided proper warnings, information, and
10 instructions for the drug in accordance with generally recognized and prevailing standards in
11 existence at the time.

12 **Fourth Defense**

13 4. At all relevant times, Defendants' warnings and instructions with respect to the use of
14 Celebrex® conformed to the generally recognized, reasonably available, and reliable state of
15 knowledge at the time the drug was manufactured, marketed, and distributed.

16 **Fifth Defense**

17 5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the
18 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

19 **Sixth Defense**

20 6. Plaintiffs' action is barred by the statute of repose.

21 **Seventh Defense**

22 7. Plaintiffs' claims against Defendants are barred to the extent Plaintiffs were
23 contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and
24 any recovery by Plaintiffs should be diminished accordingly.

25 **Eighth Defense**

26 8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or
27 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the
28 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not

1 liable in any way.

2 **Ninth Defense**

3 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
4 intervening causes for which Defendants cannot be liable.

5 **Tenth Defense**

6 10. Any injuries or expenses incurred by Plaintiffs were not caused by Celebrex®, but were
7 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act
8 of God.

9 **Eleventh Defense**

10 11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs .

11 **Twelfth Defense**

12 12. A manufacturer has no duty to warn patients or the general public of any risk,
13 contraindication, or adverse effect associated with the use of a prescription medical product.
14 Rather, the law requires that all such warnings and appropriate information be given to the
15 prescribing physician and the medical profession, which act as a “learned intermediary” in
16 determining the use of the product. Celebrex® is a prescription medical product, available only
17 on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs’
18 treating and prescribing physicians.

19 **Thirteenth Defense**

20 13. The product at issue was not in a defective condition or unreasonably dangerous at the
21 time it left the control of the manufacturer or seller.

22 **Fourteenth Defense**

23 14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit
24 for its intended use and the warnings and instructions accompanying Celebrex® at the time of
25 the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved
26 usages.

27 **Fifteenth Defense**

28 15. Plaintiffs’ causes of action are barred in whole or in part by the lack of a defect as the

1 Celebrex® allegedly ingested by Plaintiffs was prepared in accordance with the applicable
2 standard of care.

3 **Sixteenth Defense**

4 16. Plaintiffs' alleged injuries/damages, if any, were the result of misuse or abnormal use of
5 the product Celebrex® after the product left the control of Defendants and any liability of
6 Defendants is therefore barred.

7 **Seventeenth Defense**

8 17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of
9 Defendants.

10 **Eighteenth Defense**

11 18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent
12 conditions unrelated to Celebrex®.

13 **Nineteenth Defense**

14 19. Plaintiffs knew or should have known of any risk associated with Celebrex®; therefore,
15 the doctrine of assumption of the risk bars or diminishes any recovery.

16 **Twentieth Defense**

17 20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are
18 preempted in accordance with the Supremacy Clause of the United States Constitution and by
19 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

20 **Twenty-first Defense**

21 21. Plaintiffs' claims are barred in whole or in part under the applicable state law because
22 the subject pharmaceutical product at issue was subject to and received pre-market approval by
23 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

24 **Twenty-second Defense**

25 22. The manufacture, distribution, and sale of the pharmaceutical product referred to in
26 Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes,
27 and Plaintiffs' causes of action are preempted.

Twenty-third Defense

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. Defendants affirmatively aver that the imposition of punitive damages in this case

1 would violate Defendants' rights to procedural due process under both the Fourteenth
2 Amendment of the United States Constitution and the Constitutions of the States of California,
3 Minnesota, Florida, Washington, Wisconsin, and Michigan, and would additionally violate
4 Defendants' rights to substantive due process under the Fourteenth Amendment of the United
5 States Constitution.

6 **Thirty-first Defense**

7 31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and
8 Fourteenth Amendments to the United States Constitution.

9 **Thirty-second Defense**

10 32. The imposition of punitive damages in this case would violate the First Amendment to
11 the United States Constitution.

12 **Thirty-third Defense**

13 33. Plaintiffs' punitive damage claims are preempted by federal law.

14 **Thirty-fourth Defense**

15 34. In the event that reliance was placed upon Defendants' nonconformance to an express
16 representation, this action is barred as there was no reliance upon representations, if any, of
17 Defendants.

18 **Thirty-fifth Defense**

19 35. Plaintiffs failed to provide Defendants with timely notice of any alleged
20 nonconformance to any express representation.

21 **Thirty-sixth Defense**

22 36. To the extent that Plaintiffs' claims are based on a theory providing for liability without
23 proof of causation, the claims violate Defendants' rights under the United States Constitution.

24 **Thirty-seventh Defense**

25 37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and
26 labeling with respect to the subject pharmaceutical products were not false or misleading and,
27 therefore, constitute protected commercial speech under the applicable provisions of the United
28 States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of Minnesota, Florida, Washington, Wisconsin, Michigan, and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and

1 instructions with respect to the product's use in the package insert and other literature, and
2 conformed to the generally recognized, reasonably available, and reliable state of the
3 knowledge at the time the product was marketed.

4 **Fortieth Defense**

5 40. The claims asserted in the Complaint are barred because Celebrex® was designed,
6 tested, manufactured, and labeled in accordance with the state-of-the-art industry standards
7 existing at the time of the sale.

8 **Forty-first Defense**

9 41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon
10 information and belief, such injuries and losses were caused by the actions of persons not
11 having real or apparent authority to take said actions on behalf of Defendants and over whom
12 Defendants had no control and for whom Defendants may not be held accountable.

13 **Forty-second Defense**

14 42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
15 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
16 intended, and was distributed with adequate and sufficient warnings.

17 **Forty-third Defense**

18 43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches,
19 waiver, and/or estoppel.

20 **Forty-fourth Defense**

21 44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the
22 pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases or
23 illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were
24 independent of or far removed from Defendants' conduct.

25 **Forty-fifth Defense**

26 45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
27 did not proximately cause injuries or damages to Plaintiffs.

28

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Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiffs would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs.

Fifty-second Defense

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug

Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs’ claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA’s implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiffs’ claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiffs’ misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiffs’ recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive

1 damages is also barred under California Civil Code § 3294(b).

2 **Fifty-eighth Defense**

3 58. Plaintiffs' claim for punitive damages is barred pursuant to Minn. Stat. § 549.191.

4 **Fifty-ninth Defense**

5 59. Defendants plead the applicability of the Washington Products Liability Act, RCW 7.72
6 et seq., and specifically aver that Plaintiffs' common law claims are preempted by the statute
7 and must be dismissed.

8 **Sixtieth Defense**

9 60. Plaintiffs' fraud-based claims, if any, are not stated with particularity as required by
10 Rule 1.120 of the Florida Rules of Civil Procedure.

11 **Sixty-first Defense**

12 61. Plaintiffs' claims are barred because Celebrex® was designed, manufactured, and
13 marketed in accordance with the state of the art at the time of manufacture per section
14 768.1257, Florida Statutes.

15 **Sixty-second Defense**

16 62. Celebrex® is not defective or unreasonably dangerous, and Defendants are not liable
17 because, at the time of sale or distribution of the Celebrex® alleged to have been used by
18 Plaintiffs, Defendants had complied with applicable regulations of the federal Food & Drug
19 Administration and are entitled to application of section 768.1256, Florida Statutes.

20 **Sixty-third Defense**

21 63. Plaintiffs' injuries and damages, if any, were proximately caused by the negligence or
22 fault of Plaintiff, or persons or parties whose identities are unknown at this time, and such
23 comparative negligence or fault is sufficient to proportionately reduce or bar Plaintiffs'
24 recovery. Thus, Defendants are entitled to have their liability to the Plaintiffs, if any, reduced
25 as a result of the negligence or fault of said persons or entities, pursuant to the provisions of
26 section 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant
27 to sections 768.31 and 768.81, Florida Statutes, judgment must be entered on the basis of
28 Defendants' percentage of fault, taking into account the percentage of fault attributable to all

1 other persons, whether or not a party hereto, and not on the basis of joint and several liability.
2 The persons or entities referred to in this paragraph that are presently unknown to Defendants
3 will be identified in a timely manner consistent with *Nash v. Wells Fargo*, 678 So. 2d 1262
4 (Fla. 1996).

5 **Sixty-fourth Defense**

6 64. Plaintiffs fail to state a claim for violation of The Florida Deceptive and Unfair Trade
7 Practices Act ("FDUTPA").

8 **Sixty-fifth Defense**

9 65. FDUTPA does not apply to claims for personal injuries, and, accordingly, Plaintiffs'
10 FDUTPA claim is improper and should be dismissed.

11 **Sixty-sixth Defense**

12 66. The acts or practices of which Plaintiffs complain were and are required or specifically
13 permitted by federal or state law. Therefore, Plaintiffs' FDUTPA claim is barred, fails to state
14 a claim, and should be dismissed with prejudice.

15 **Sixty-seventh Defense**

16 67. Plaintiffs lack standing because the answering Defendants did not engage in deceptive
17 conduct with regard to Plaintiff or otherwise.

18 **Sixty-eighth Defense**

19 68. The product in question was approved as safe and effective by the FDA and the labeling
20 for said product was in compliance with FDA's approval at the time the products left the
21 control of one or more Defendants and hence, Plaintiffs' claims are barred by MCL
22 600.2946(5).

23 **Sixty-ninth Defense**

24 69. Plaintiffs' claim for non-economic damages is capped pursuant to MCL 600.2946a.

25 **Seventieth Defense**

26 70. To the extent Plaintiffs prove that the products in question caused or contributed to any
27 injury they may have suffered, which is denied by these Defendants, these Defendants should
28 not be liable to warn as Plaintiffs cannot prove that the scientific, technical or medical

1 information that was reasonably available at the time was known or should have been known by
2 the Defendants. MCL 600.2948.

3 **Seventy-first Defense**

4 71. Defendants assert all of the protections and defenses afforded them, and Plaintiffs'
5 claims of liability or damages are limited pursuant to the Michigan Products Liability Act
6 including specifically, but not limited to MCL 600.2946 through MCL 600.6306, including
7 MCL 600.2946, MCL 600.2946(a), MCL 600.2947, MCL 600.2948, MCL 600.2956, MCL
8 600.2957 and MCL 600.2959.

9 **Seventy-second Defense**

10 72. The product alleged to have caused damages may not have been used in the manner and
11 for the purposes intended. Such improper use and/or abuse of the product for an unforeseeable
12 purpose and in an unforeseeable manner may have proximately caused or contributed to the
13 alleged injuries, if any, and therefore there is no recovery available against Defendants pursuant
14 to MCL 600.2947.

15 **Seventy-third Defense**

16 73. Plaintiffs' claim for non-economic damages is barred for the reason that Plaintiffs'
17 percentage of comparative fault is greater than the aggregate fault of the Defendants and non-
18 parties hereto, pursuant to MCL 600.2959 and MCL 600.6306; but that to the extent allowable,
19 must be reduced in total or part pursuant to 600.2946(a).

20 **Seventy-fourth Defense**

21 74. The claims set forth in Plaintiffs' Complaint are barred in that the product in question
22 was provided to a sophisticated user. In this case, the "user" would include any prescribing
23 physician.

24 **Seventy-fifth Defense**

25 75. Plaintiffs failed to make every reasonable effort to mitigate, prevent and/or reduce their
26 alleged damages, injuries, and monetary losses.

27 **Seventy-sixth Defense**

28 76. Plaintiffs' claims, part of Plaintiffs' claims, or evidence relating to Plaintiffs' claims

1 may be barred in whole or in part due to possible spoliation of evidence by Plaintiffs, or those
2 within Plaintiffs' control or with full knowledge of Plaintiffs.

3 **Seventy-seventh Defense**

4 77. Any claims for punitive damages are barred in that they are not allowable under
5 Michigan law. To the extent that they are allowed contrary to Michigan law, such claims further
6 violate Defendants' constitutional rights under the following clauses of the United States
7 Constitution, as well as any similar provisions under the Michigan Constitution: Commerce
8 Clause, Contracts Clause, Supremacy Clause, Due Process, Takings Clause, Excessive Fines
9 and Equal Protection.

10 **Seventy-eighth Defense**

11 78. Defendants reserve the right to supplement their assertion of defenses as they continue
12 with their factual investigation of Plaintiffs' claims.

13 **V.**

14 **PRAYER**

15 WHEREFORE, Defendants pray for judgment as follows:

- 16 1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
- 17 2. That the Complaint be dismissed;
- 18 3. That Defendants be awarded their costs for this lawsuit;
- 19 4. That the trier of fact determine what percentage of the combined fault or other liability
20 of all persons whose fault or other liability proximately caused Plaintiffs' alleged
21 injuries, losses, or damages is attributable to each person;
- 22 5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater
23 than an amount which equals their proportionate share, if any, of the total fault or other
24 liability which proximately caused Plaintiffs' injuries and damages; and
- 25 6. That Defendants have such other and further relief as the Court deems appropriate.

June 13, 2008

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

June 13, 2008

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By: _____/s/_____

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